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PATENT TRADEMARK OFFICE

CHAPTER II

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO. CLAIMED	INTERNATIONAL FILING DATE	PRIORITY DATE
PCT/NL99/00369	14 JUNE 1999	18 JUNE 1998

TITLE OF INVENTION

ASSEMBLY FOR FIXING A TUBE FOR MEDICAL PURPOSES TO A PATIENT'S MOUTH

APPLICANT(S)

JOHANNES ALPHONSUS **VAN HEGELSOM**

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US

NOTE. The completion of those filing requirements that can be made at a time later than 30 months from the priority date results from the Commissioner exercising his judgment under the authority granted under 35 USC 371(d). The filing receipt will show the actual date of receipt of the last item completing the entry into the national phase. See 37 C.F.R. §1.491 which states: "An international application enters the national state when the applicant has filed the documents and fees required by 35 USC 371(c) within the periods set forth in § 1.494 and § 1.495."

CERTIFICATION UNDER 37 C.F.R. 1.10*

*(Express Mail label number is **mandatory**.)*
(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date DECEMBER 14, 2000, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number EE784102663US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

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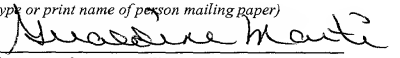

Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

***WARNING:** *Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

EXPRESS MAIL LABEL
NO.:EE784102663US

WARNING: *Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. §1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing - See 37 C.F.R. §1.8.*

NOTE: *Documents and fees must be clearly identified as a submission to enter the national state under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111. 37 C.F.R. § 1.494(f).*

1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

   a. [X] This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).

   b. [X] The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2.Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
[ ]*	TOTAL CLAIMS	27 - 20 =	7	x $ 18.00 =	$126.00
	INDEPENDENT CLAIMS	1 - 3 =		x $ 80.00 =	
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + $270.00				
BASIC FEE**	[ ] U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: [ ] and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(2) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 CFR 1.492(a)(4)) ..... $100.00 [ ] and the above requirements are not met (37 CFR 1.492(a)(1)) ..... $690.00 [X] U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: [ ] has been paid (37 CFR 1.492(a)(2)) ..... $710.00 [ ] has not been paid (37 CFR 1.492(a)(3)) ..... $1,000.00 [X] where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 CFR 1.492(a)(5)) $860.00				
	Total of above Calculations				986
SMALL ENTITY	Reduction by ½ for filing by small entity, if applicable. Affidavit must be filed. (note 37 CFR 1.9, 1.27, 1.28)				-
	Subtotal				
	Total National Fee				$493.00
	Fee for recording the enclosed assignment document $40.00 (37 CFR 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				
TOTAL	Total Fees enclosed				$493.00

*See attached Preliminary Amendment Reducing the Number of Claims.

i. [X] A check in the amount of $493.00 to cover the above fees is enclosed.
ii. [ ] Please charge Account No. _____ in the amount of $ _____.
A duplicate copy of this sheet is enclosed.

***WARNING:* *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).*

WARNING: *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.*

3. [X] A copy of the International application as filed (35 U.S.C. 371(c)(2)):

NOTE: *Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.*

a. [ ] is transmitted herewith.
b. [ ] is not required, as the application was filed with the United States Receiving Office.
c. [X] has been transmitted
i. [X] by the International Bureau.
Date of mailing of the application (from form PCT/IB/308): _____.
ii. [ ] by applicant on _____.
Date

4. [X] A translation of the International application into the English language (35 U.S.C. 371(c)(2)):
a. [X] is transmitted herewith.
b. [ ] is not required as the application was filed in English.
c. [ ] was previously transmitted by applicant on _____.
Date
d. [ ] will follow.

5. [X] Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

a. [ ] are transmitted herewith.
b. [ ] have been transmitted
   i. [ ] by the International Bureau.
   Date of mailing of the amendment (from form PCT/IB/308): _____.
   ii. [ ] by applicant on _____.
   Date
c. [X] have not been transmitted as
   i. [X] applicant chose not to make amendments under PCT Article 19.
   Date of mailing of Search Report (from form PCT/ISA/210): Sept. 9, 2000.
   ii. [ ] the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. [X] A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):
a. [ ] is transmitted herewith.
b. [ ] is not required as the amendments were made in the English language.
c. [X] has not been transmitted for reasons indicated at point 5(c) above.

7. [X] A copy of the international examination report (PCT/IPEA/409)
[X] is transmitted herewith.
[ ] is not required as the application was filed with the United States Receiving Office.

8. [X] Annex(es) to the international preliminary examination report
a. [X] is/are transmitted herewith.
b. [ ] is/are not required as the application was filed with the United States Receiving Office.

9. [X] A translation of the annexes to the international preliminary examination report
a. [X] is transmitted herewith.
b. [ ] is not required as the annexes are in the English language.

10. [X] An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115
    a. [ ] was previously submitted by applicant on _____. Date
    b. [X] is submitted herewith, and such oath or declaration
        i. [ ] is attached to the application.
        ii. [X] identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. 1.70.
    c. [ ] will follow.

Other document(s) or information included:

11. [X] An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):
    a. [X] is transmitted herewith.
    b. [ ] has been transmitted by the International Bureau.
    Date of mailing (from form PCT/IB/308): _____.
    c. [ ] is not required, as the application was searched by the United States International Searching Authority.
    d. [ ] will be transmitted promptly upon request.
    e. [ ] has been submitted by applicant on _____. Date

12. [X] An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98:
    a. [X] is transmitted herewith.
    Also transmitted herewith is/are:
    [X] Form PTO-1449 (PTO/SB/08A and 08B).
    [X] Copies of citations listed.
    b. [ ] will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).
    c. [ ] was previously submitted by applicant on _____. Date

13. [ ] An assignment document is transmitted herewith for recording.

A separate [ ] "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or [ ] FORM PTO 1595 is also attached.

_____
_____
_____

14. [X] Additional documents:
    a. [ ] Copy of request (PCT/RO/101)
    b. [X] International Publication No. WO 99/65553
        i. [X] Specification, claims and drawing
        ii. [ ] Front page only
    c. [X] Preliminary amendment (37 C.F.R. § 1.121)
    d. [ ] Other

_____
_____
_____

15. [X] The above checked items are being transmitted
    a. [X] before 30 months from any claimed priority date.
    b. [ ] after 30 months.

16. [ ] Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on
_____, namely:

_____
_____
_____

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1 17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

[X] The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425___.

[X] 37 C.F.R. 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 C F.R. § 1 495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

[ ] 37 C.F.R. 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must

only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

[X] 37 C.F.R. 1.17 (application processing fees)
[X] 37 C.F.R. 1.17(a)(1)-(5)(extension fees pursuant to § 1.136(a).
[X] 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))

NOTE: *Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).*

NOTE: *37 C.F.R. 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.*

[ ] 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

SIGNATURE OF PRACTITIONER

Reg. No.: 25,858

WILLIAM R. EVANS
(type or print name of practitioner)

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LADAS & PARRY
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26 WEST 61ST STREET
NEW YORK, NEW YORK 10023

Customer No.:

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: JOHANNES ALPHONSUS **HEGELSOM**, et al

For: ASSEMBLY FOR FIXING A TUBE FOR MEDICAL PURPOSES TO A PATIENT'S MOUTH

Attorney Docket No.: U 013111-0

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to an examination of this application on the merits, please amend the application as follows:

IN THE CLAIMS

Please cancel Claims 1-27.

Please add the following new claims:

-- 28. Assembly for fixing a tube for medical purposes to a patient's mouth, the tube being fixed to the patient's head, comprising a tube clamping means which can be attached to the tube in a detachable manner, which tube clamping means is provided

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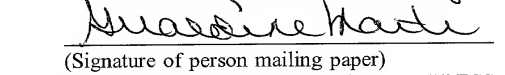
CERTIFICATE UNDER 37 1.10

I hereby certify that this paper is being deposited with the United States Postal Service on this date DECEMBER 14, 2000 in an envelope as "EXPRESS MAIL POST OFFICE TO ADDRESSEE" Mailing Label Number EK462879885US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231

GERALDINE MARTI
(Type or print name of person mailing paper)



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with first positioning means, further comprising flexible, detachable securing means that are to be arranged around the patient's head and are provided with second positioning means that can be connected to the first positioning means, to position the tube clamping means during use, the tube clamping means comprising a first tube clamping member, which is solid with and formed as one unity with the first positioning means, and a second tube clamping member, which is hingeable with respect to the first tube clamping member for movement between an open position, in which the tube clamping means can freely receive the tube, and a closed clamping position, in which the tube is kept clamped with respect to the tube clamping means and the first positioning means, the first tube clamping member being arranged in order to extend under the tube during use.

29. Assembly according to claim 28, the first positioning means comprising a positioning plate which is substantially transverse to the tube clamping means and which is formed as one unity with the first clamping member.

30. Assembly according to claim 28, wherein the second positioning means comprise an occipital strap and a number of flexible, detachable attachment straps extending between the occipital strap and the first positioning means, the occipital strap being provided with slots for letting through the attachment straps, the attachment straps being adjustable as to length, and can be secured on themselves on both sides of the patients' head.

31. Assembly according to claim 30, the first positioning means comprising a positioning plate which is substantially transverse to the tube clamping means and which is formed as one unity with the first clamping member,

the attachment straps being permanently connected to the plate when said plate is manufactured.

32. Assembly according to claim 30, the straps that are adjustable as to length being adjustable as to length by means of Velcro.

33. Assembly according to claim 30, each attachment strap adjustable as to length being connected to the plate at two locations and having a recess in between them.

34. Assembly according to claim 28, the occipital strap at both ends being provided with a recess to let through the ends of the attachment straps that are adjustable as to length.

35. Assembly according to claim 34, the occipital strap being provided with means for stiffening the recesses, such as a little rod extending along the recess, said rod being preferably situated at the attachment strap side of the recess.

36. Assembly according to claim 34, the recesses being situated at the level of the corners of the jaw.

37. Assembly according to claim 30, the occipital strap being accommodated in a hat or cap to be placed over the patient's head.

38. Assembly according to claim 37, the cap being provided with recesses

for the patient's ears.

39. Assembly according to claim 36, the cap extending over the head and being provided with means for attachment of care or monitor lines at the front/upper side.

40. Assembly according to claim 28, the first and the second tube clamping members being hingeable about an axis which is substantially parallel to the tube to be clamped.

41. Assembly according to claim 40, the two tube clamping members being formed by two half oval rings, which along one edge are connected to each other by means of a hinge, preferably a living hinge.

42. Assembly according to claim 28, the two tube clamping members in their clamping position being securable to each other by means of catching means, preferably comprising a snap finger on the one clamping member and a cam on the other clamping member, the snap finger then being detachably snappable behind the cam.

43. Assembly according to claim 28, both tube clamping members at their insides being provided with a number of tube fixation protrusions directed inwards.

44. Assembly according to claim 29, the positioning plate being provided with a slot to let the tube through when arranging the plate, the plate preferably being substantially U-shaped.

45. Assembly according to claim 28, the first positioning means comprising slots, for letting through attachment straps belonging to the second positioning means.

46. Assembly according to claim 45, the slots being vertically aligned.

47. Assembly according to claim 29, the first positioning means comprising slots, for letting through attachment straps belonging to the second positioning means, four slots being arranged in the plate, mainly at the vertices of a rectangle.

48. Assembly according to claim 29, the positioning plate being adapted to the anatomy of the patient's face.

49. Assembly according to claim 29, a bite member for between the patient's teeth being provided at the rear of the positioning plate.

50. Assembly according to claim 28, the first tube clamping member being provided with a continuous recess, which extends, at least at the outer end of the clamping member, over its entire wall cross-section for allowing through a pilot tube on the tube.

51. Assembly according to claims 49, the first tube clamping member being provided with a continuous recess, which extends, at least at the outer end of the clamping member, over its entire wall cross-section for allowing through a pilot tube on the tube, the plate and the bite member being provided with recesses aligned with the aforementioned recess for allowing through a pilot tube on the tube, the recess in the bite member being

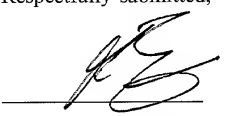
continuous over the entire length and its wall cross-section.

52. Assembly according to claim 49, the bite member being substantially U-shaped in cross-section.

53. Assembly according to claim 49, the bite member and the plate being provided with concave surfaces and edges, respectively, at its sides.

54. Assembly according to claim 28, the tube clamping member being entirely made from synthetic material, preferably polypropene.

Respectfully submitted,



WILLIAM R. EVANS
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REG.NO.25858(212)708-1930

Assembly for fixing a tube for medical purposes to a patient's mouth.

The invention relates to an assembly for fixing a tube for medical purposes to a patient's mouth, the tube being fixed to the patient's head.

When anaesthetizing a patient an endotracheal tube or respiration tube has to be inserted in the patient's windpipe or a larynx mask has to be inserted in the patient's throat. After intubation the annular space between the tube and the windpipe has to be closed off so that the patient breathes only through the tube. This closing off is effected with a balloon, which is inflated after insertion. In order that the tube with the balloon is not moved in the windpipe, which could lead to damage of the windpipe, the tube has to be fixed to the patient's head.

Usually the tube is fixed with the help of a band aid and/or a ribbon. This, however, has the disadvantage that a band aid no longer adheres well when it becomes moist, and that when removing the band aid the skin could get damaged. When using a ribbon it has to be tied tightly around the neck, which results in pressure on the underlying structures and the possibility that the skin among others near the corners of the mouth can get cut in. A further disadvantage is that the band aid or the ribbon cannot be removed quickly. Danger of contamination is another drawback.

In US patent specification 4.249.529 a tube clamp is shown, which with the help of two cords can be secured to the patient's head. The tube clamp comprises two semi-circular clamping members, which are attached to a plate via arms that are inclined towards each other and which are connected to each other by means of a hinge. The tube is clamped by

pressing both clamping members in a direction opposite to the coinciding component of the arms, as a result of which the clamping members hinge towards each other into a closing position. This activity is rather difficult to control, as a result of which a longitudinal displacement of the tube during the process of letting it clamp is possible here. Also the track over which the tube has to be moved in transverse direction is substantial, because of which the danger of displacement only increases. The result may be that the tube, of which the anaesthetist had first noticed that its end was correctly situated near the fork of the lungs, moves to such an extent that it extends in one of the lungs with one end. The other lung is then sidetracked, which entails major risks for the patient during the operation. Moreover, the efficiency of the balloon closing may be insufficient.

From the literature several other devices are known to fix an endotracheal tube to the patient's head. None of these known constructions, however, offers a satisfactory solution in practice. In particular the ease of placing and quick removal of the device are not achieved.

It is an object of the invention to provide an assembly for fixing a tube for medical purposes in a patient's mouth, which can easily and reliably be placed by the anaesthetist. It is another object of the invention to provide an assembly which can quickly be removed from the tube. It is yet another object to provide an assembly which can partly be arranged on the patient's head in advance. It is a further object of the invention to provide an assembly which after being used once can be disposed of. It is yet a further object of the invention to provide an assembly which can be made in a simple and cheap manner. These and further objects appear from the description below.

One or more of these objects are achieved with an assembly for fixing a tube for medical purposes to a patient's mouth, the tube being fixed to the patient's head, comprising a tube clamping means which can be attached

to the tube in a detachable manner, which tube clamping means is provided with first positioning means, further comprising flexible, detachable securing means that are to be arranged around the patient's head and are provided with second positioning means that can be connected to the first positioning means, to position the tube clamping means during use, the tube clamping means comprising a first tube clamping member, which is solid with the first positioning means, and a second tube clamping member, which is hingeable with respect to the first tube clamping member for movement between an open position, in which the tube clamping means can freely receive the tube, and a closed clamping position, in which the tube is kept clamped with respect to the tube clamping means and the first positioning means.

The tube clamping means need not be arranged until after the patient has been intubated. With the help of detachable securing means and the second positioning means the tube clamping means can be positioned by means of the first positioning means, the first clamping member solid therewith stabilizing the tube to be clamped during clamping. The anaesthetist can focus his attention to rotating the single other clamping member. In this manner unwanted tube displacements which may be damaging to the patient, can be prevented.

Preferably the first tube clamping member is arranged in order to extend under the tube during use, so that this clamping member constitutes as it were a bearing for the tube that is not (entirely) clamped yet.

Preferably the two tube clamping members are formed by two half oval rings, which along one edge are connected to each other by means of a hinge, preferably a living hinge. It is furthermore preferred when the first and the second tube clamping members are hingeable about an axis which is substantially parallel to the tube to be clamped.

Preferably the two tube clamping members are securable to each other in their clamping position by means of catching means, preferably comprising a snap finger at the one clamping member and a cam at the other clamping member, the snap finger then being detachably snappable behind the cam. In this way the tube clamping means can be closed and opened in an easy and therefore controllable manner.

In the unlikely event of a tube being used that does not exactly fit, fixation against axial displacement of the tube is improved when both tube clamping members are provided at their insides with a number of inwardly directed tube fixation protrusions. With the help of these fixation protrusions the clamped tube is held additionally and cannot be pulled through the tube fixation means.

Preferably one of the tube clamping means is provided with a recess for letting through a pilot tube (for supply and discharge of air to and from the balloon sleeve) on the tube, so that the pilot tube cannot be clamped off. It is preferred here when the first tube clamping member is provided with a continuous recess, which extends, at least at the outer end of the clamping member, over its entire wall cross-section. It is prevented in this way that with a curved tube the pilot tube is pressed closed as yet at the outer end of the clamping member. This is of vital importance. When the balloon sleeve is insufficiently inflated namely, a part of the stomach contents may end up in the lung. On the other hand, when the sleeve remains inflated to hard, tissue damage resulting in scars may occur.

According to an advantageous embodiment the tube clamping member is entirely made from synthetic, preferably from polypropene. As a result the tube clamping means can easily and cheaply be manufactured by injection moulding, as a result of which it can be used as a disposable product. Also the material is well adjusted to the human body. The clamping members in themselves are relatively rigid.

Preferably the hinge is a living hinge, so that the hinge can be made during injection moulding without additional measures being necessary. In this way the tube clamping means remains cheap.

Preferably the first positioning means are provided on a plate which is substantially transverse to the tube clamping means, which plate preferably is provided with a slot to let the tube through when arranging the plate, the plate preferably being substantially U-shaped. With the help of the plate the tube clamping means can easily be placed at the patient's head, whereas the plate further provides good support against the patient's head.

Preferably the first positioning means comprise -preferably vertical- slots, for letting through attachment straps belonging to the second positioning means. For optimal transfer of forces thus four slots can be arranged in the plate, mainly at the vertices of a rectangle.

According to a preferred embodiment the plate is adapted to the anatomy of the patient's face, so that the pressure on the patient's face can never become to high.

Preferably a bite member for between the patient's teeth is provided at the rear of the plate. Because of this bite member the patient will not accidentally be able to bite in the tube, as a result of which the passage opening becomes too small and the tube could get damaged.

Preferably the bite member is substantially U-shaped in cross-section to allow the tube through. The U-shaped bite member connects to the U-shaped plate, so that the whole can be slid around the tube from the chin side after which the tube clamping means can be clamped around the tube. After detaching the tube clamping means the plate with the bite member can easily be removed again.

Preferably the bite member and the plate are provided with concave surfaces and edges, respectively, at their sides, so that as much room as possible is left to get into the mouth, for instance with medical instruments.

Preferably the plate and the bite member are provided with recesses aligned with the aforementioned recess for allowing through a pilot tube on the tube. The recess in the bite member can be continuous over the entire length and its wall cross-section, so that the pilot tube has ample possibilities to extend into the mouth in an unclamped manner.

According to a further development the second positioning means comprise an occipital strap and a number of flexible, detachable attachment straps extending between the occipital strap and the first positioning means. With the -flat- strap around the head and the -flat- adjustable straps the plate with the tube clamping means can be positioned and kept in place well, with a correctly adjustable tightness of the straps around the head. The straps are soft and do not adhere to the user's head, so that the skin will not be damaged or cut in.

Preferably the straps that are adjustable as to length run through the recesses in the plate and they can be secured on themselves. The straps adjustable as to length are thus attached to the plate and do not need to be separately arranged.

According to another preferred embodiment the straps adjustable as to length are accommodated to the plate when said plate is manufactured. For instance when injection moulding the plate the ends of the straps can be laid in the matrix, after which the plate is formed around the ends.

Preferably the straps adjustable as to length can be adjustable as to length by means of Velcro.

Preferably each strap that is adjustable as to length is connected to the plate on two locations and has a recess in between them. As a result of the connection on two locations on both sides the plate can be positioned in a very stable manner, and because of the recesses in the straps the inside of the mouth can still be reached along the plate.

The occipital strap in an advantageous manner is provided at both ends with a recess to let through the ends of the attachment straps that are adjustable as to length, the occipital strap -in order to have the straps abut tightly and in a flat manner- preferably being provided with means for stiffening the recesses, such as a little rod extending along the recess, said rod preferably being situated at the side of the recess facing the attachment strap. In this way the occipital strap remains tight there and the forces are transferred better. Quickly untying in case of an emergency is also improved.

For an optimal transfer of forces the recesses are situated at the level of the corners of the jaw. The forces are then transferred, at least for the larger part, on the jaw corner and deflected upwards for a small part, via the temple. This is much more comfortable for the patient and better for the blood circulation, because there is no pressure on the blood vessels below and adjacent to the jaw. In addition these areas are then free for insertion of monitor lines, such as for instance in the neck.

Preferably the occipital strap is accommodated in a hat or cap to be placed over the patient's head. In this way the occipital strap is immediately in the correct place after arranging the cap or hat, and the strap cannot be displaced during use. The cap does not only give ease and certainty of placement, it also performs a function in counteracting the loss of warmth through evaporation and radiation. Usually the loss of warmth via the head is about 20-30%. The cap thus provides a passive means for keeping the body at the right temperature.

Preferably the strap also runs along the lower side of the patient's ears during use.

Preferably the hat is provided with recesses for the patient's ears, so that ear operations and the like can be performed. Moreover the blood saturation of the ears is ensured. The position of the ears can also be checked, which is of importance when the patient is lying with his ear on a pillow. One is then able to see from aside whether the ear is in the correct position. This is of importance, because the ears are end organs and may die off in a situation in which they are pinched off. Another advantage is that measuring can now still be performed on the ear, for instance a pulsoxy meter, for assessing the blood circulation.

The cap can be arranged in advance. The attachments for the mouthpiece are situated on the side, so that without moving the patient's head the mouthpiece can be attached with the help of the Velcro strips.

The cap can furthermore fulfil another function, when it extends over the head and at the front/upper side is provided with means for attachment of either care or monitor lines. The cap thus also provides surfaces available for securing catheters/probes and other lines. In this manner a drip line can be arranged in the neck, said line being attached on the side of the cap. Stomach and temperature probes can be laid over the head towards the nose, and be secured on top of the cap with the help of the Velcro strips.

The invention furthermore relates to a tube clamping means suitable for the assembly of the invention, as well as to the above-mentioned hat or cap.

The invention will be elucidated on the basis of an exemplary embodiment, referring to the attached drawing.

Figure 1 schematically shows a patient, the assembly according to the

invention being used and the assembly comprising schematically shown tube clamping means, positioning means and attachment means.

Figure 2 shows the tube clamping means according to the invention in perspective view.

Figure 3 shows the tube clamping means according to figure 2 in front view.

Figure 1 schematically shows the patient's head 1, a respiration tube 10 being inserted in the windpipe through the patient's mouth. Around the patient's head 1 an assembly 20 is arranged for fixing the respiration tube 10. The assembly 20 consists of a tube clamp 30, a positioning plate 40, two attachment straps 50, and a pulling strap 61 which is accommodated in a cap 60.

The tube clamp 30 and the positioning plate 40 are shown in more detail in figures 2 and 3.

Figure 2 shows the tube clamp 30 and the positioning plate 40 in perspective view. The tube clamp 30 consists if a moveable half oval ring 31 which can be moved with respect to a half oval ring 32 which is solid with the plate 40, in which both half oval rings are connected to each other by means of a living hinge 33. The movable half oval ring 31 has a snap finger 34, which can hook about a cam 35 on the solid half oval ring 32. The snap finger 34 is elastic in order to remove the snap finger 34 from the cam 35, so that the half oval ring 31 can be opened with respect to the half oval ring 32. Both half oval rings 31 and 32 are of such a size that they can clamp the respiration tube 10 between them in the closed position of the tube clamp 30. The inside of the member 31 is provided with a fixation protrusion 36, and the inside of the solid member 32 is provided with two fixation protrusions to additionally fix the respiration

tube 30 in longitudinal direction, in addition to the frictional forces. The solid half oval ring 32 is provided with a recess 37 extending transverse through the wall in order to accommodate a pilot tube (see 73, figure 1), which runs along the respiration tube 10, for a large part loose at the concave bent lowerside thereof, without pressing the pilot tube closed.

The positioning plate 40 consists of a plate member 41 of a substantially rectangular shape, four vertical slots 42 being arranged in the corners, for the attachment of the attachment straps 50 (see figure 1). The plate member 41 is provided with a U-shaped slot 43 to let the respiration tube 10 through to the tube clamp 30 and is provided with recesses 44 on both sides, so that the plate member 41 leaves sufficient space around the respiration tube 10 after arrangement to get into the patient's mouth with for instance medical instruments. At the rear of the plate member 41 a bite member 45 is arranged which is formed as one unity therewith, which bite member is in line with the half oval ring 32 and which is provided with a U-shaped recess in order to accommodate the respiration tube 10, so that the tube 10 cannot be squeezed together by the patient's teeth. The bite member 45 is provided with recesses at the sides which connect to the recesses 44 in the plate member 41.

As can be seen in figures 2 and 3 the recess 37 is continued in the plate member 41 and the bite member 45, the recess 37 also extending through the entire wall thickness in the bite member.

Figure 3 shows the parts of the tube clamp 30 and the positioning plate 40 in front view.

The tube clamp 30, the positioning plate 40 and the bite member 45 are manufactured as one unity from a suitable synthetic, such as polypropene. The mouthpiece, consisting of the tube clamp 30, the positioning plate 40 and the bite member 45 can then be made by means of injection moulding.

Polypropene here has the advantage that it can be made transparent, so that the information on the respiration tube 10 can still be read.

The attachment straps 50 have two fingers 51 at one end, which are separated by a recess 52. The attachment straps 50 are made from a flexible, soft material such as Medifoam ®, and the fingers 51 are pulled through the slots 52 in the positioning plate 41 and turned and secured on themselves, for instance by sewing. Because of the recesses 52 it is possible to get into the patient's mouth for instance with medical instruments. The other end of the attachment straps 50 is provided with Velcro, the last part 43 for instance being provided with looped tape, and the part preceding it being provided with barbed tape.

The assembly further consists of a cap 60, which fits rather closely to the patient's head 1, and which leave the patient's ears free. At the lower edge of the cap 60 an occipital strap or pulling strap 61 is accommodated in the cap 60, which pulling strap 61 can run underneath the patient's ears behind the patient's head and which pulling strap 61 is provided with a slot 62 at its ends where the part 53 of the attachment strap 50 can be inserted through. At the front side of the slot 62 a little rod is accommodated in the material of the cap 60, in order to maintain the shape of the slot 62 and to distribute the forces better.

The use of the assembly is as follows.

The hat can already be placed on the patient's head during the preparations of the operation. Subsequently the respiration tube 10 is arranged in the patient's windpipe. When said respiration tube 10 is positioned correctly, the positioning plate 40 is slid around the tube 10, the U-shaped recess 43 moving around the tube 10, until the tube 10 lies in the half oval ring 32. The pilot tube 73 then extends downwards through the recess 37 free from the tube. The bite member 45 is placed between

the patient's teeth. The ends 53 of the attachment straps 50 are inserted through the slots 62 in the pulling strap 61, and the ends 53 are pulled such and folded down to such an extent that the pulling strap 61 is brought at the right tension. Subsequently the strap portion 53 with looped tape is attached on the strap portion 54 with barbed tape. The positioning plate 40 is fixed on the patient's head in that way. Finally the respiration tube 10, after the anaesthetist has ascertained that its end is situated in the correct location, is fixed in the tube clamp 30 by rotating the half oval ring 31 to the solid half oval ring 32 and then to secure it with the snap finger 34 about the cam 35.

The advantage of fixing in this order is that the movements of the respiration tube 10 can be kept limited to a minimum in this way.

The advantage of the cap 60 is that from a hygienic point of view it retains the hair, and ensures that the pulling strap 61 cannot slide down from the jaw corner to the neck. Furthermore cooling down of the head is counteracted. It is further expected that a patient will have less objections to a cap than to just wearing a pulling strap. The cap 60 can furthermore be useful in securing care lines, such as the stomach catheter 72, which with the help of Velcro 71 cooperating with the Velcro surface 70 on the cap 60 can be secured (see figure 1).

The assembly is easy to detach by operating the snap finger 34 and pulling the Velcro loose from the portion 53. In case of an emergency the respiration tube 10 can be detached from the patient with the mouthpiece still on it, just by untying the Velcro on both sides.

Claims (twice amended)

1. Assembly for fixing a tube for medical purposes to a patient's mouth, the tube being fixed to the patient's head, comprising a tube clamping means which can be attached to the tube in a detachable manner, which tube clamping means is provided with first positioning means, further comprising flexible, detachable securing means that are to be arranged around the patient's head and are provided with second positioning means that can be connected to the first positioning means, to position the tube clamping means during use, the tube clamping means comprising a first tube clamping member, which is solid with and formed as one unity with the first positioning means, and a second tube clamping member, which is hingeable with respect to the first tube clamping member for movement between an open position, in which the tube clamping means can freely receive the tube, and a closed clamping position, in which the tube is kept clamped with respect to the tube clamping means and the first positioning means, the first tube clamping member being arranged in order to extend under the tube during use.

2. Assembly according to claim 1, the first positioning means comprising a positioning plate which is substantially transverse to the tube clamping means and which is formed as one unity with the first clamping member.

3. Assembly according to claim 1 or 2, wherein the second positioning means comprise an occipital strap and a number of flexible, detachable attachment straps extending between the occipital strap and the first positioning means, the occipital strap being provided with slots for letting through the attachment straps, the attachment straps being adjustable as

to length, and can be secured on themselves on both sides of the patients' head.

4. Assembly according to claim 3 whem dependent from claim 2, the attachment straps being permanently connected to the plate when said plate is manufactured.

5. Assembly according to claim 3 or 4, the straps that are adjustable as to length being adjustable as to length by means of Velcro.

6. Assembly according to claim 3, 4 or 5, each attachment strap adjustable as to length being connected to the plate at two locations and having a recess in between them.

7. Assembly according to any one of the claims 3-6, the occipital strap at both ends being provided with a recess to let through the ends of the attachment straps that are adjustable as to length.

8. Assembly according to claim 7, the occipital strap being provided with means for stiffening the recesses, such as a little rod extending along the recess, said rod being preferably situated at the attachment strap side of the recess.

9. Assembly according to claim 7 or 8, the recesses being situated at the level of the corners of the jaw.

10. Assembly according to any one of the claims 3-9, the occipital strap being accommodated in a hat or cap to be placed over the patient's head.

11. Assembly according to claim 10, the cap being provided with recesses for the patient's ears.

12. Assembly according to claim 9 or 10, the cap extending over the head and being provided with means for attachment of care or monitor lines at the front/upper side.

13. Assembly according to any one of the preceding claims, the first and the second tube clamping members being hingeable about an axis which is substantially parallel to the tube to be clamped.

14. Assembly according to claim 13, the two tube clamping members being formed by two half oval rings, which along one edge are connected to each other by means of a hinge, preferably a living hinge.

15. Assembly according to any one of the preceding claims, the two tube clamping members in their clamping position being securable to each other by means of catching means, preferably comprising a snap finger on the one clamping member and a cam on the other clamping member, the snap finger then being detachably snappable behind the cam.

16. Assembly according to any one of the preceding claims, both tube clamping members at their insides being provided with a number of tube fixation protrusions directed inwards.

17. Assembly according to claim 2, the plate being provided with a slot to let the tube through when arranging the plate, the plate preferably being substantially U-shaped.

18. Assembly according to any one of the preceding claims, the first positioning means comprising slots, for letting through attachment straps belonging to the second positioning means.

19. Assembly according to claim 18, the slots being vertically aligned.

20. Assembly according to claim 2 and 18 or 19, four slots being arranged in the plate, mainly at the vertices of a rectangle.

21. Assembly according to claim 2 or 20, the plate being adapted to the anatomy of the patient's face.

22. Assembly according to claim 2, a bite member for between the patient's teeth being provided at the rear of the plate.

23. Assembly according to any one of the preceding claims, the first tube clamping member being provided with a continuous recess, which extends, at least at the outer end of the clamping member, over its entire wall cross-section for allowing through a pilot tube on the tube.

24. Assembly according to claims 22 and 23, the plate and the bite member being provided with recesses aligned with the aforementioned recess for allowing through a pilot tube on the tube, the recess in the bite member being continuous over the entire length and its wall cross-section.

25. Assembly according to claim 22, the bite member being substantially U-shaped in cross-section.

26. Asembly according to claim 22 or 25, the bite member and the plate being provided with concave surfaces and edges, respectively, at its sides.

27. Assembly according to any one of the preceding claims, the tube clamping member being entirely made from synthetic, preferably polypropene.

(AF/NG 990)

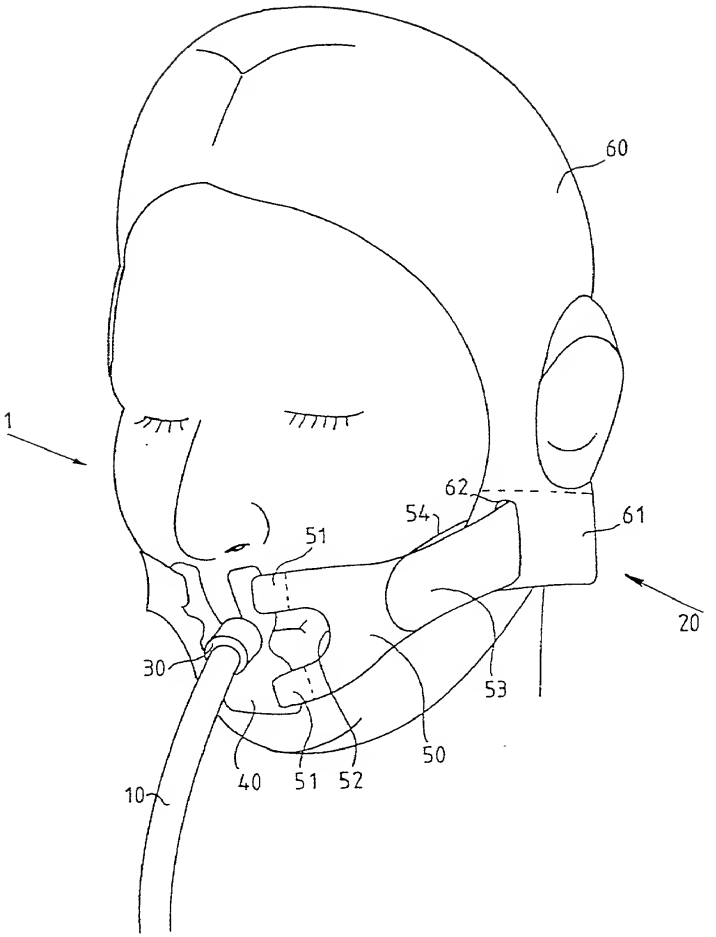

FIG.1

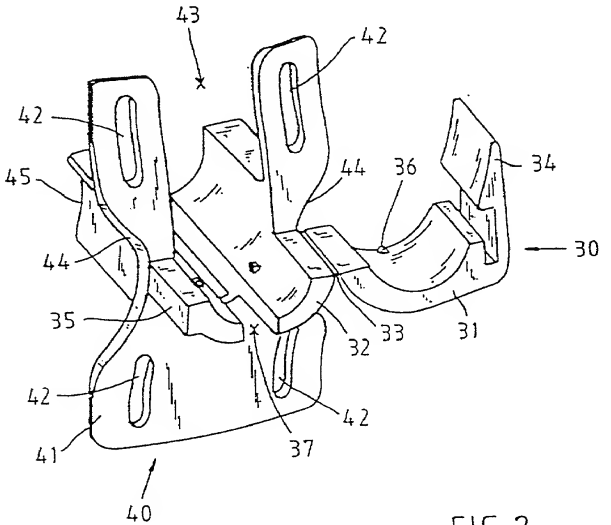

FIG. 2

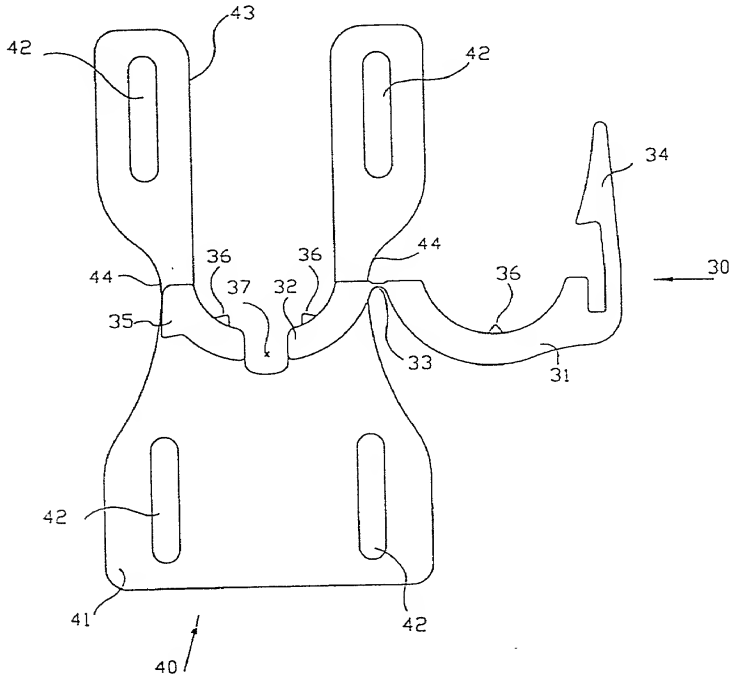

FIG. 3

Practitioner's Docket No. U 013111-0 ***PATENT***

Optional Customer No. Bar Code

00140
00140
PATENT TRADEMARK OFFICE

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

[ ] original.
[ ] design.

NOTE: With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. Section 714.16, 7th Ed.

[ ] supplemental.

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

[X] national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

NOTE: See 37 C.F.R. Section 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

[ ] divisional.
[ ] continuation.

NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. Section 1.53(b) (application filing requirements-nonprovisional application).

[ ] continuation-in-part (C-I-P).

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INVENTORSHIP IDENTIFICATION

WARNING: *If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

ASSEMBLY FOR FIXING A TUBE FOR MEDICAL PURPOSES TO A PATIENT'S MOUTH

SPECIFICATION IDENTIFICATION

The specification of which:

(complete (a), (b), or (c))

(a) [ ] is attached hereto.

NOTE: *"The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:*

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) [ ] was filed on _____, [ ] as Application No. _____
[ ] and was amended on _____ (if applicable).

NOTE: *Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. Section 1.67.*

NOTE: *"The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 C.F.R. Section 1.63:*

(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
(B) serial number and filing date;
(C) attorney docket number which was on the specification as filed;
(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.
M.P.E.P. Section 601.01(a), 7th ed.

(c) [X] was described and claimed in PCT International Application No. PCT/NL99/00369 _____ filed on _____14 June 1999_____ and as amended under PCT Article 19 on _____*(if any)*.

SUPPLEMENTAL DECLARATION (37 C.F.R. Section 1.67(b))

(complete the following where a supplemental declaration is being submitted)

[ ] I hereby declare that the subject matter of the

[ ] attached amendment
[ ] amendment filed on _____.

was part of my/our invention and was invented before the filing date of the original application, above identified, for such invention.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, Section 1.56,

(also check the following items, if desired)

[ ] and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

[ ] in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. Section 1.98.

PRIORITY CLAIM (35 U.S.C. Section 119(a)-(d))

NOTE: "The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by Section 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. Section 119(b) must be filed in the case of an interference (Section 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in Section 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner; or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. Section 1.55(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) [ ] no such applications have been filed.
(e) [X] such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. SECTION 119(a)-(d)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING DAY, **MONTH**, YEAR	PRIORITY CLAIMED UNDER 35 USC 119
NL	1009440	18 June 1998	[X]YES [ ]NO
			[ ]YES [ ]NO
			[ ]YES [ ]NO
			[ ]YES [ ]NO
			[ ]YES [ ]NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. Section 119(e))

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	**FILING DATE**
/ _____	_____
/ _____	_____
/ _____	_____

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. SECTION 120

[ ] The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), *IF ANY,* FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. Section 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

JOSEPH H. HANDELMAN, 26179

JOHN RICHARDS, 31053

RICHARD J. STREIT, ~~25765~~

PETER D. GALLOWAY, ~~27885~~

IAN C. BAILLIE, ~~24090~~

THOMAS F. PETERSON, 24790

RICHARD P. BERG, 28145

JULIAN H. COHEN, 20302

WILLIAM R. EVANS 25858

JANET I. CORD, 33778

CLIFFORD J. MASS, 30086

CYNTHIA R. MILLER, 34678

(Check the following item, if applicable)

[ ] I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

[ ] Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.63(d)(4)." Section 601.03, M.P.E.P., 7th Ed

SEND CORRESPONDENCE TO

Ladas & Parry
26 West 61st Street
New York, N.Y. 10023

DIRECT TELEPHONE CALLS TO:
(Name and telephone number)

(complete the following if applicable)

Since this filing is a [ ] continuation [ ] divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other document.

NOTE: Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 C.F.R. Section 1.63(a)(3).

NOTE: Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997,

Full name of sole or first inventor
Johannes Alphonsus VAN HEGELSOM
(Given Name) *(Middle Initial or Name)* *Family (Or Last Name)*

Inventor's signature X

Date 11 DEC 2000 **Country of Citizenship** Netherlands

Residence Brouwersweg 19 – 7351 TJ HOENDERLOO - The Netherlands

Post Office Address same as above

,,,,,,

Full name of second joint inventor, if any

(Given Name) *(Middle Initial or Name)* *Family (Or Last Name)*

Inventor's signature _____

Date _____ **Country of Citizenship** _____

Residence _____

Post Office Address _____

,,,,,,

Full name of third joint inventor, if any

(Given Name) *(Middle Initial or Name)* *Family (Or Last Name)*

Inventor's signature _____

Date _____ **Country of Citizenship** _____

Residence _____

Post Office Address _____

(check proper box(es) for any of the following added page(s) that form a part of this declaration)

[ ] **Signature** for fourth and subsequent joint inventors. *Number of pages added* _____

* * *

[ ] **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____

* * *

[ ] **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 C.F.R. Section 1.47. *Number of pages added* _____

* * *

[ ] Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 C.F.R. Section 1.47)

* * *

[ ] Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

[ ] Number of pages added _____

* * *

[ ] Authorization of practitioner(s) to accept and follow instructions from representative.

(If no further pages form a part of this Declaration,
then end this Declaration with this page and check the following item)

[X] This declaration ends with this page.